PATENT SPECIFICATION

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(54) BLOOD OXYGENATOR

(71) We, THE UNIVERSITY OF STRATHCLYDE, a British University incorporated by Royal Charter, of 204 George Street, Glasgow G1 1XW, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to a blood oxygenator.

Artificial lungs incorporating a gas-permeable membrane between the blood and the gas are capable of prolonged cardiopulmonary support with minimal blood damage. If the blood flow is laminar and rectilinear (as in the majority of membrane units presently available) then the artificial lung performance is limited, not by the membrane permeablility, but by gas diffusion in the blood. It is well known that the convective mixing in the blood phase greatly improves the performance. Although turbulent blood flow would be a very effective form of mixing, severe blood trauma would result. Consequently some kind to laminar mixing is necessary to minimise trauma.

According to the present invention there is provided a blood oxygenator comprising a pair of cylinders, one within the other defining a space therebetween, an oxygen permeable membrane fixed to each of the opposed cylinder walls within the space to form between the membranes a flow channel for blood and between each membrane and adjacent cylinder wall a flow path for oxygen, inlet and outlet means for blood and for oxygen and drive means for rotating at least one of the cylinders.

When a liquid is made to flow axially through an annular space between two cylinders placed one inside the other and at least one of the cylinders is rotated, the flow pattern which develops depends on a number of factors. The axial Reynolds number R is defined as Vd/υ where V is the average axial velocity, d is the annular gap and υ is the kinematic viscosity of the liquid. The Taylor number T is defined as $\Omega^2 r_1 d^3/\upsilon^2$ where Ω is the angular velocity of the cylinder, r_1 is the radius of the inner cylinder and d and υ are as defined above.

If the axial Reynolds number is zero, 4 major regimes may be identified:— (1) For low Taylor numbers the flow is pure shear and of a Couette Type. (2) At a critical Taylor number, T_c, secondary toroidal laminar circulations develop, the strength of these secondary circulations increasing as the Taylor number increases above this critical value until a second critical value is reached. (3) When this latter critical value is exceeded, the secondary flow consists of toroidal vortices with superposed turbulence, and (4) When the Taylor number is increased still further, the toroidal vortices disappear and the flow is turbulent.

The second regime is the one of interest in the present invention. This regime is useful because it possesses secondary transverse laminar mixing and the strength of these circulations can be controlled by adjusting the angular velocity of the inner cylinder.

The oxygenator may include a gas-penetrable membrane support member located between each of the cylinder walls and the adjacent membrane so as to hold the membrane in spaced relationship to the walls.

The annular spaces between the inner cylinder and its adjacent membrane and between the outer cylinder and its adjacent membrane provide flowpaths for oxygen. When these spaces contain a support member it is clear that such a support should be such that the flowpath will be open to the passage of oxygen therethrough.

The membrane support member may be of porous plastics material such as a reticular polyurethane foam, or it may have the form of a net or plastics material or it may be simply projections extending outwards from the cylinder wall, which projections hold the membrane in spaced relationship to the wall.

The membrane may be adhered to the

cylinder wall or to the porous support by the use of an adhesive. If no support is used it may be attached to the wall by means of a compression seal ring. Also it may be attached to the porous support by heat sealing.

The inner cylinder is normally the one of the pair which would be rotated although, subject to certain conditions, rotation of either will induce mixing. The cylinders may be mounted concentrically and driven on the common axis, and this would normally be the set-up, but if an eccentrically mounted cylinder pair is used and the inner cylinder is rotated such that its membrane surface rolls on the surface of the outer cylinder membrane pumping action which can be utilised in an artificial heart-lung machine assembly is obtained. Additionally, one of the cylinders may be rotationally oscillated. Another modification is that there may be provided surface irregularities in the membraneous walls of the blood flow channel walls to assist mixing of the blood.

An embodiment of the invention will now be described by way of example with reference to the accompanying drawings in which:—

Fig. 1 is a sectional view through an oxygenator of this invention;

Fig. 2 is a cross-section on line A—A shown in Fig. 1 through the concentric cylinder portions; and

Fig. 3 shows the cylinder arrangement of Fig. 2 for a flow-inducing oxygenator.

Referring to Figs. 1 and 2, a blood oxygenator 1 has a pair of concentric cylinders 2, 3. The outer cylinder 2 of the pair is provided on its internal surface with a sheet 4 of reticular polyurethane foam containing some epoxy resin for added rigidity. The foam 4 provides a support for an oxygen-permeable membraneous sheet 5 which is placed thereon to cover the foam. The inner cylinder 3 of the pair is likewise provided on its outer surface with a sheet of foam 6 to provide a membrane support for a membraneous sheet 7 which is fitted on the foam 6. Thus there is defined between the membranes 5 and 7 a flow channel for blood: between each cylinder (2 and 3) and its associated membrane sheet (5 and 7) there is a flow path 9, 10 for oxygen, the flow paths 9 and 10 being filled with recticular foam sheets 4 and 6.

The inner cylinder 3 is hollow: one end is closed by a conical end cap 11 and the other by a circular end plate 12. The cylinder 3 has upper and lower circumferential rim portions 13 and 13' providing a recessed seat for the support member 6 and its membrane 7 to secure them to the curved surface of cylinder 3. The circular end plate 12 has a centrally located pipe 14 extending therethrough into the interior of the cylinder 3 and a second pipe 15 extending coaxially through the central pipe 14 toward the remote end of cylinder 3. At the remote end of the cylinder 3 the second pipe 15 connects with a circumferential inlet port 16 in the cylinder wall 3 behind the foamed plastics support member 6.

The pipe 14 extending centrally through the circular end plate 12 opens into the interior of the hollow cylinder 3 which has a gas outlet port 17 in the cylinder wall 3 behind the support member 6.

The series of passageways described above define a flowpath for oxygen gas; it is fed in through the second pipe 15 through which it flows, via the port 16, through the reticular support member 6 in an axial direction toward the opposite end of cylinder 3. It leaves via the port 17 and the central pipe 14 in the circular end plate 12.

The outer cylinder 2 is open ended and has an oxygen inlet 19 extending circumferentially around the cylinder 2 near one end. The cylinder 2 has upper and lower rim portions 18 and 18' providing a recessed seat for the membrane support member 4. The circumferential inlet opens into the space occupied by the reticular support member 4. Openings 20 are provided in the cylinder wall 2 near the opposite end to provide outlet means for oxygen from the support member 4. The oxygen may flow, therefore, into the reticular support member 4 from the circumferential inlet 19 through the support 4 in an axial direction and out via the outlet ports 20 in the cylinder wall 2.

A conical-section closure member 21 having an outlet 22 at its apex sits upon one end of the outer cylinder 2 and encloses the conical end cap 11 of the inner cylinder 2. The outer conical closure member 2 is spaced from the inner conical end cap 11 to define a space 23 therebetween which communicates with the blood flow channel 8 defined between the membranes 5 and 7.

The double cylinder assembly described above sits on a base plate 24. The base plate 24 has a central port 25 for passage therethrough of the central pipe 14 and its associated coaxial pipe 15.

Around the periphery of the base plate 24 there is a recessed rim portion 26 providing a seat for the outer cylinder 2.

A blood inlet port is provided by a pipe 27 which extends through the outer cylinder wall 2 in a generally tangential direction and communicates with the annular blood flow channel 8.

The base plate 12 of the inner cylinder 3 is located so that its central pipe 14 and the coaxial second pipe 15 therein, passes through the central port 25 in the base plate

24. The central pipe 14 is connected to suitable rotary drive means indicated by 28 in the drawing.

Annular sealing means 29 are located around the central pipe 14 to seal the space between inner cylinder base plate 12 and base plate 24. It is made of rubber or resilient plastics material.

The central port 25 in base plate 24 has bearing means 33 for the pipe 14.

The membraneous sheets 5 and 7 are secured to the exposed faces of support members 4 and 6 by use of an adhesive or by heat sealing.

The oxygenator 1 sits upon a mounting bench 30 and is supported by a number (conveniently four) of support pillars 31 which engage recesses in the bench 30 and corresponding recesses in the base plate 24. The bench 30 has an aperture 32 for passage of oxygen inlet and outlet pipes 14 and 15 therethrough.

Locating members 34 are provided within the pipe 14 to lock the pipe 15 to pipe 14 so that it will rotate therewith. The members 34 are small plugs of plastics material having a central hole for receiving pipe 15 and several through-passages to permit outflow of oxygen through pipe 14.

Fig. 3 is the same section as Fig. 2 and all the reference numerals correspond, but it shows the relative positions of the cylinders 2 and 3 required to produce a flow-inducing arrangement. The centre O of inner cylinder 3 is offset from the centre X of outer cylinder 2. When cylinder 2 is rotated about an axis which passes through centre X the cylinder 3 rolls around the inner surface of outer cylinder 2 in a flow-inducing action. This action may implement or even replace any external blood pump used for pumping blood from the patient to the apparatus.

In use, blood is fed from a patient's vein through the tangential inlet 27 into the blood flow channel 8 defined between the membranes 5 and 7 whence it flows axially upwards into the space 23 defined between the outer conical-section closure member 21 and the inner conical end cap 11. Blood flows out of the oxygenator via the outlet 22 at the apex of the conical-section closure member 21.

Oxygen is fed into the oxygenator through two inlets namely, the circumferential oxygen inlet 19 in the outer cylinder 2, and through the pipe 15 which extends coaxially through the central pipe 14 in the circular end plate 12 of the inner cylinder 3. From the circumferential inlet 19 oxygen flows axially downward through the support member 4 on the outer cylinder 2 and leaves the apparatus via the openings 20 in the cylinder wall 2. From the coaxial pipe 15 the oxygen flows via the circumferential port 16 into the reticular support 6 on the inner cylinder 3, axially downwards through the support 6 whence it flows inwardly through the ports 17 into the interior of cylinder 3 and leaves the apparatus through central pipe 14.

The inner cylinder 3 is rotated by the drive means 28. The flow rate of blood and the angular velocity of the cylinder are selected according to the theoretical considerations described hereinbefore to induce in the flow secondary currents in the form of vortices. The vortices promote mixing of the blood in the flow channel 8 thereby promoting oxygenation thereof on the surfaces of the membranes 5 and 7 through which oxygen permeates from the oxygen passing through the porous support members 4 and 6.

WHAT WE CLAIM IS:—

1. A blood oxygenator comprising a pair of cylinders, one within the other defining a space therebetween, an oxygen permeable membrane fixed to each of the opposed cylinder walls within the space to form between the membranes a flow channel for blood and between each membrane and adjacent cylinder wall a flow path for oxygen, inlet and outlet means for blood and for oxygen and drive means for rotating at least one of the cylinders.

2. An oxygenator according to claim 1, comprising also gas-penetrable support member interposed between each oxygen-permeable membrane and cylinder wall to hold the membrane in spaced relationship from the wall.

3. An oxygenator according to claim 2, in which the gas-penetrable support member is made of a foamed plastics material.

4. An oxygenator according to claim 1, or 2 or 3, in which the inner cylinder is a hollow cylinder closed at one end and having an end plate at the opposite end provided with a vent-pipe and including a circumferential gas inlet near one end and communicating with the oxygen flowpath located between the inner cylinder and the membrane, pipework for supply of oxygen to said inlet and extending from said inlet for connection to an external oxygen supply, outlet apparatus communicating the said oxygen flowpath with the cylinder interior and an outlet pipe leading from the cylinder interior.

5. An oxygenator according to any preceding claim, including a base plate providing a seat for one end of the outer cylinder, a closure plate at the opposite end of the outer cylinder and having a blood outlet located therein and being spaced from the inner cylinder end-plate to permit outflow of blood from the blood flowpath formed between the membranes, and in which a circumferential blood inlet is

provided in the outer cylinder wall for inflow of blood into the inter-membrane flowpath.

6. An oxygenator according to any preceding claim, in which the outer cylinder has near one end a circumferential oxygen inlet which communicates with the oxygen flowpath formed between the internal wall of the outer cylinder and the adjacent membrane, and oxygen outlet ports at the opposite end for outflow of oxygen.

7. A blood oxygenator comprising a pair of cylinders, one within the other forming a space therebetween, a pair of gas-penetrable support members within the space and fixed to the opposed cylinder walls, an oxygen-permeable membrane fixed to each support member, oxygen inlets extending to the support members and outlets extending therefrom providing a flowpath for oxygen, a blood inlet extending into the inter-membrane space and an outlet extending therefrom providing a flowpath for blood, and means for rotating the inner cylinder.

8. A blood oxygenator according to claim 7, in which the inner cylinder is mounted for concentric rotation within the outer.

9. An oxygenator according to claim 7, in which the inner cylinder is mounted eccentrically within the outer and has means for rotation about the axis of the outer cylinder whereby the inner cylinder membrane surface rolls on the surface of the outer cylinder membrane.

10. A blood oxygenator substantially as hereinbefore described with reference to the accompanying drawings.

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1480406 COMPLETE SPECIFICATION

3 SHEETS *This drawing is a reproduction of the Original on a reduced scale*

Sheet 1

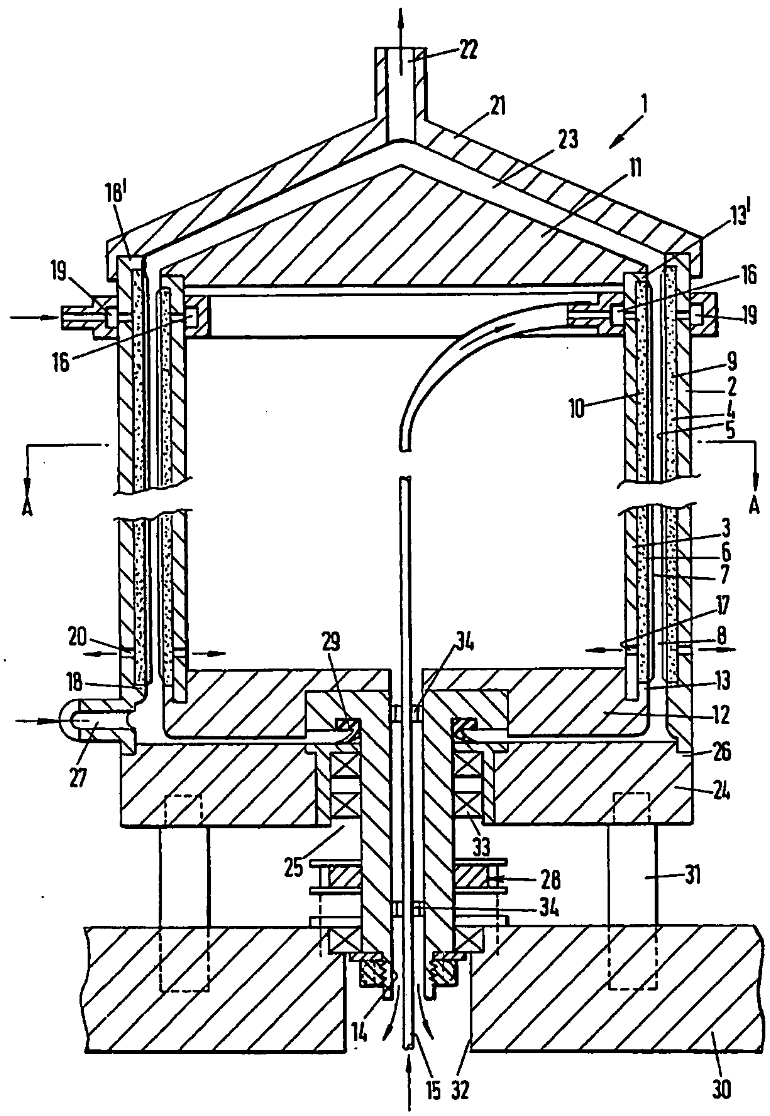

FIG.1

1480406 COMPLETE SPECIFICATION

3 SHEETS *This drawing is a reproduction of the Original on a reduced scale*

Sheet 2

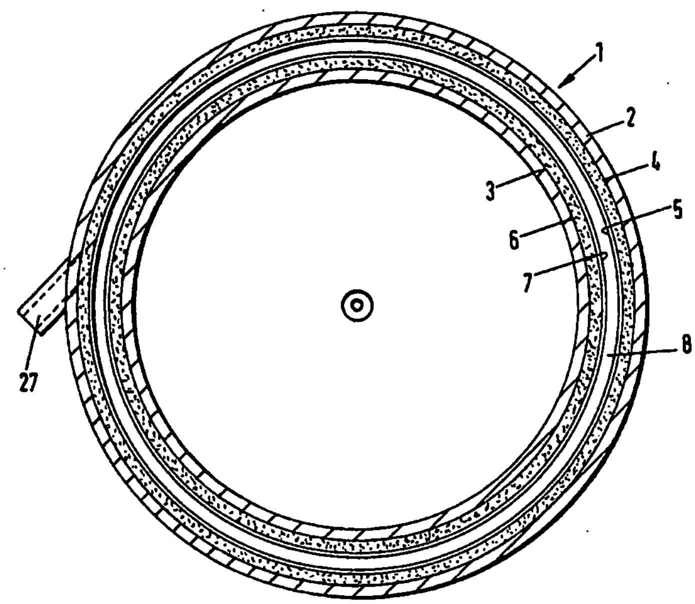

FIG.2

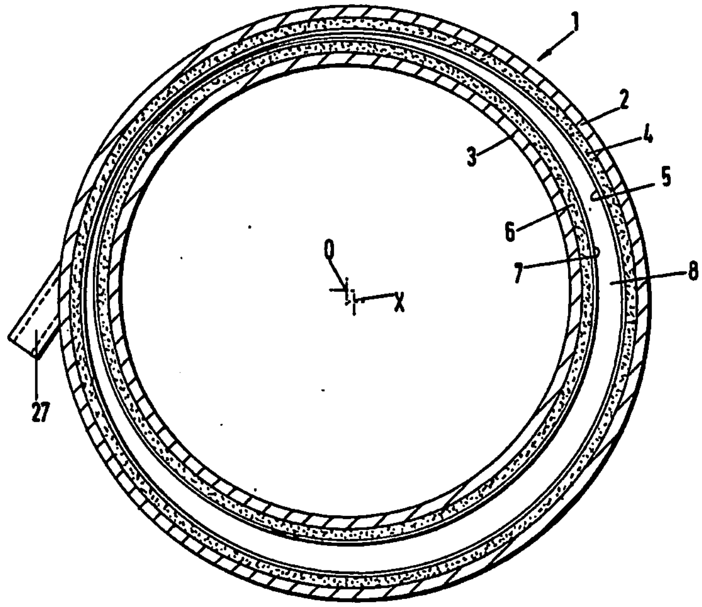

FIG. 3